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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,621	12/22/2003	Jens Bjerre Knudsen	6494.210-US	7397
23650      7590      01/28/2009 NOVO NORDISK, INC. INTELLECTUAL PROPERTY DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540				
EXAMINER				
MOELINA, ANITA C				
ART UNIT		PAPER NUMBER		
3626				
NOTIFICATION DATE		DELIVERY MODE		
01/28/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/743,621

**Applicant(s)**

KNUDSEN ET AL.

**Examiner**

ANITA MOLINA

**Art Unit**

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The following is a final action on the merits. Claims 1-46 have been cancelled and claims 47-50 are new.

#### ***Oath/Declaration***

The Oath was correctly submitted for the parent application and no new subject matter was introduced in the present application, therefore, a new Oath is not required. The copy of the previously submitted Oath was received and entered.

#### ***Response to Amendment***

The cancellation of all previous claims overcomes the previously made U.S.C. 101 and 112 rejections.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,381,577 to Brown in view of US 2003/0023461 to Quintanilla et al, hereinafter, Quintanilla and in view of *Sickle*.

*As per claim 47*, Brown teaches **a method of transmitting information about a bleeding disorder to a healthcare provide for use with one or more patients having bleeding disorders, the method comprising the steps of:**

**-providing the patient with a handheld device having a monitor with a processor** (see: column 2, lines 44-53 and column 3, lines 49-65);

**-displaying on the monitor a question** (see: column 3, lines 49-65) indicative of whether the patient has taken a hemostatic medication prior to a bleeding episode;

**-receiving an answer from the patient** (see: column 3, lines 49-65) as to whether a medication was administered before the bleeding episode began;

**-displaying on the monitor a question** (see: column 3, lines 49-65) indicative of the time from the initial occurrence of the bleeding episode to the time of an infusion of an hemostasis product;

**-receiving an answer from the patient** (see: column 3, lines 49-65) as to the time of the bleeding episode to the infusion;

**-transmitting from the hand held device to a centralized database at a location accessible to a healthcare provider information** (see: column 4, lines 1-2) relating to location of the bleeding episode, time from onset of the bleeding episode to infusion, response to the infusion.

Brown fails to specifically teach:

**-displaying on the screen one or more pictures of the human body;**

**-instructing the patient to indicate where bleeding is occurring by touching the picture in a location representative of the actual bleed;**

**-receiving from the patient information as to the patients response to the infusion.**

Quintanilla teaches displaying a picture of a human body (see: Figure 5), allowing a patient to indicate where they are bleeding by indicating a location on that picture (see: paragraph 34), and receiving information about the effects of a treatment (see: paragraph 26). It would have been obvious to one of ordinary skill in the art to include in the querying of patient information using a handheld device of Brown, the information regarding bleeding location and patient response as taught by Quintanilla because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

Brown also fails to specifically teach a handheld device with a **touch screen**. *Sickle* teaches using a Palm Pilot with a touch screen to gather patient medical information. It would have been obvious to one of ordinary skill in the art to include in the querying of patient information using a handheld device of Brown, the touch screen as taught by *Sickle* because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

The Examiner notes that the method is not affected by the type of information that is displayed and received. Therefore, no patentable weight is given to the type of information because it is nonfunctional and a new and unobvious functional relationship

between the nonfunctional material (queried information) and the substrate (the claimed method) is absent (see: MPEP 2601.01).

*As per claim 48*, Brown fails to teach the claimed method **further comprising registering information about infusions of hemostasis agents from one of the patients having a bleeding disorder, wherein the information is entered via the handheld device and wherein the information entered comprises one or more of the following: reasons for an infusion of a hemostasis product, number of infusions given in a predetermined time period, or number of bleeding episodes since last infusion of a hemostasis product.** Quintanilla teaches patients entering data in an infusion log (see: paragraph 28, Figure 9) and using this information to graph infusions for a given patient over a period of time (see: paragraph 43). It would have been obvious to one of ordinary skill in the art to include in the querying of patient information using a handheld device of Brown, the infusion log as taught by Quintanilla for the same reasons set forth for claim 47.

*As per claim 49*, Brown fails to teach the claimed method **where the patient is instructed to operate the device contemporaneously with a bleeding episode.** Sickel teaches use of a handheld device to record patient information during a pain episode of a sickle cell anemia patient (see: abstract). It would have been obvious to one of ordinary skill in the art to include in the querying of patient information using a handheld device of Brown, the use of such a device during an episode of a disease as taught by Sickel for the same reasons set forth for claim 47.

3. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0023461 to Quintanilla in view of *Sickle*.

*As per claim 50*, Quintanilla teaches a **system for collecting data relating to treating a patient having a bleeding disorder, the system comprising**

**-a handheld device having a display that displays one or more figures of the human body** (see: paragraphs 25 and 34),

**-an input mode for allowing a patient to enter location of a bleed by touching a corresponding part on the figure of the human body, the input mode allowing for entry of data relating to time from bleed to start of infusion of a self-administered hemostasis product and the input mode allowing for input of data relating to the success of the infusion in affecting the bleed** (see: paragraph 34),

**-the system being configured to transmit data collected by the handheld device from the patient to a centralized processor, the centralized processor configured to compile data from multiple handheld devices** (see: paragraph 32).

Quintanilla fails to teach a **touch screen** display. *Sickle* teaches using a Palm Pilot with a touch screen to gather patient medical information. It would have been obvious to one of ordinary skill in the art to include in the handheld device of Quintanilla, the touch screen as taught by *Sickle* because the claimed invention is merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

The Examiner notes that the system is not affected by the type of information that is displayed and received. Therefore, no patentable weight is given to the type of information because it is nonfunctional and a new and unobvious functional relationship between the nonfunctional material (queried information) and the substrate (the claimed system) is absent (see: MPEP 2601.01).

### ***Response to Arguments***

4. There were no argument to address.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANITA MOLINA whose telephone number is (571)270-3614. The examiner can normally be reached on Monday through Friday 8am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M./  
Examiner, Art Unit 3626  
1/08/2009

/Robert Morgan/  
Primary Examiner, Art Unit 3626